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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,096	12/03/1998	DANIEL B. DRACHMAN	01107.77737	8208

7590 11/16/2001

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EXAMINER
SORBELLO, ELEANOR

ART UNIT	PAPER NUMBER
1633	17

DATE MAILED: 11/16/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/205,096	DRACHMAN, DANIEL B.	
	Examin r	Art Unit	
	Eleanor Sorbello	1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10/15/01 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *41-65*.

   Claim(s) withdrawn from consideration: _____.
8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: The amended claims do not narrow the scope of the claims and the same issues remain. Therefore the rejections made in the Final Office Action mailed 7/13/01 stand for reasons of record.

Applicants argue that the instant invention is directed to a method of ablating T cells which had been modified previously by a nucleotide encoding the autoantigen and when reintroduced into the individual another product such as Fas ligand or FADD is added. The narrower claims however recite that the Fas ligand or FADD is also expressed by the T cells. Therefore, it is still unclear if the product which is detrimental to the T cells will be expressed prior to administration and then the question is will the T cells be ablated even before they are administered? Applicants argue that they have shown in vitro data to work and therefore ex vivo therapy should be directly extrapolatable from these data, because the expression is outside the individual. However in unpredictable fields, when the prior art, in this case ex vivo gene therapy is not enabled across the board, the onus is on the applicants to support that which is claimed by analogous experimentation. Applicants further argue that DNAs encoding numerous auto-antigens are available in the public databases and therefore one of skill should without undue experimentation be able to transform T cells from a patient with the auto-antigen that afflicts the individual and then reintroduce the T cells thereby alleviating the disease. Applicants argue that immunotherapy and gene supplementation are mutually exclusive and that if some clinical trials in ex vivo therapy are ongoing, that the instant invention is therefore enabled. However, for the same reasons discussed herein and stated in the Office Action dated 7/13/01, the claims stand rejected.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER